

Office Action states:

Claim 79 is drawn to an isolated trichodiene synthase comprising the amino acid sequence of SEQ ID NO. 2, or a fragment thereof that has trichodiene synthase activity. This is a genus claim in terms of any fragment of SEQ ID NO. 2 having trichodiene synthase activity. Claim 87 is drawn to an isolated trichodiene synthase which is a fragment of an amino acid sequence having at least 97% identity to SEQ ID NO. 2 and trichodiene synthase activity. This is a genus claim in terms of any fragment having 97% identity to SEQ ID NO. 2 and trichodiene synthase activity. The specification mentions only the full length trichodiene synthase from *Fusarium venenatum*. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the fragments having trichodiene synthase activity based on the teachings in the specification. ... Therefore, the specification does not describe the claimed fragments in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these fragments at the time of filing the present application. Thus, the written description requirement has not been satisfied.

This rejection is respectfully traversed.

Applicants respectfully note that a fragment is defined on page 22, lines 8-11, of the specification: "A fragment of SEQ ID NO. 2 is a polypeptide having one or more amino acids deleted from the amino and/or carboxyl terminus of this amino acid sequence. Preferably, a fragment contains at least 290 amino acid residues, more preferably at least 320 amino acid residues, and most preferably at least 350 amino acid residues." Claims limited to the amino acid sequence of SEQ ID NO. 2 would not adequately protect the inventors. One of ordinary skill in the art could make a fragment of SEQ ID NO. 2 by simply removing one or more amino acids from the amino and/or carboxyl terminus of the polypeptide. Thus, based on the teachings of the present application, one skilled in the art could make such a fragment while retaining the trichodiene synthase activity thereby circumventing the literal scope of Applicants' patent rights. In the new claims, claim 97 recites "An isolated functional fragment of the trichodiene synthase of SEQ ID NO. 2, wherein one or more amino acids are deleted from the amino and/or carboxyl terminus of SEQ ID NO:2."

For the foregoing reasons, Applicants submit that the new claims overcome the rejections under 35 U.S.C. § 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 87-89 under 35 U.S.C. § 112, First Paragraph

Claims 87-89 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a fragment of an amino acid sequence having at least 97% identity to SEQ ID NO. 2 and having trichodiene synthase activity, does not reasonably provide enablement for an amino acid sequence having at least 97% identity to SEQ ID NO. 2 which lacks trichodiene synthase activity. The Office Action states that this rejection can be overcome by amending the claim to recite "An isolated functional trichodiene synthase ..." and deleting the phrase "that has trichodiene synthase activity" from the end of the claim.

Applicants have cancelled claims 87-89 and added new claim 101 which recites "An isolated trichodiene synthase obtained from a *Fusarium venenatum* strain comprising an amino acid sequence which differs by one, two,

three, four, or five amino acids from the amino acid sequence of SEQ ID NO:2." Support for this claim is found on page 21, lines 19-30, of the specification.

For the foregoing reasons, Applicants submit that the new claims overcome the rejections under 35 U.S.C. § 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejections.

III. The Rejection of Claims 85 and 89 under 35 U.S.C. § 112, First Paragraph

Claims 85 and 89 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Specifically, the Office Action states:

While it is clear that the strain has been deposited at the ATCC, it is not clear that it was deposited by the instant inventors. Since the person/company who deposited the strain may withdraw it from the ATCC at any time, it is not clear the recited strain would be freely available for the one wishing to practice the claimed invention. Furthermore, it is not clear that the strain would be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whatever period is longer, or that access to the material will be available during the pendency of the patent application. Consequently, a biological deposit for patenting purposes is required.

This rejection is respectfully traversed.

In the amendment of September 28, 2001, Applicants asserted that the ATCC 20334 strain recited in the claims is "known and readily available" and, therefore, under 37 C.F.R. 1.802(b), "[b]iological material need not be deposited, inter alia, if it is known and readily available to the public ..." Applicants did not deposit the strain. Applicants further quoted the comments on interpreting and applying the rules regarding the terms "known and readily available" in 37 C.F.R. 1.802(b) as set forth at page 232 of 1122 Official Gazette 223-38. In particular, the comments regarding the terms "known and readily available" in 37 C.F.R. 1.802(b) set forth at page 232 state:

Even where access to biological material is required to satisfy these statutory requirements, a deposit may not be necessary if access sufficient to satisfy these requirements is otherwise available. ... For example, applicant could show that the biological material is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available - neither concept alone is sufficient....

By showing that a biological material is known and readily available or by making a deposit in accordance with these rules, applicant does not guarantee that such biological material will be available forever. Public access during the term of the patent may affect the enforceability of the patent. Although there is a public interest in the availability of a deposited biological material during and after the period of enforceability of the patent, the examiner need not be unduly concerned about continued access to the public. Unless there is a reasonable basis to believe that the biological material will cease to be available during the life of the patent, the examiner should accept current availability as satisfying the requirement. The incentives provided by the patent

system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee. *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969) (emphasis added).

Particularly noteworthy in the above comments is the statement: "Unless there is a reasonable basis to believe that the biological material will cease to be available during the life of the patent, the examiner should accept current availability as satisfying the requirement." Applicants previously enclosed a copy of the web pages from the ATCC web site (www.atcc.org) showing that ATCC 20334 is readily available and can be ordered from the ATCC for a fee. Applicants submit that the pages establish that the ATCC 20334 strain is currently available and there is no reasonable basis to believe that the biological material will cease to be available during the life of the patent and, therefore, Applicants have complied with 37 C.F.R. 1.802(b).

For the foregoing reasons, Applicants submit that the new claims overcome the rejections under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejections.

IV. The Rejection of Claims 87-89 under 35 U.S.C. § 112, Second Paragraph

Claims 87-89 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because claim 87 recites "having" as a transitional phrase which is vague and indefinite as it has not been defined legally as open or closed transitional language. The Office Action suggests amending the claim to recite "comprising" or "consisting of" as appropriate.

Applicants have cancelled claims 87-89, but have taken the suggestion into consideration in new claim 101 which recites "comprising."

For the foregoing reasons, Applicants submit the new claims overcome the rejections under 35 U.S.C. § 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of Claims 79 and 87 under 35 U.S.C. § 102

Under 35 U.S.C. § 102(b), claims 79 and 87 stand rejected as being anticipated by Hohn *et al.* (*Molecular Plant-Microbe Interactions* 5: 249-256, 1992). The rejection is respectfully traversed.

Hohn *et al.* (*Molecular Plant-Microbe Interactions* 5: 249-256, 1992) disclose a trichodiene synthase from *Gibberella pulicaris* with a 98.8% query match with SEQ ID NO:2. The Office Action states that the "trichodiene synthase of Hohn *et al.* is a variant of SEQ ID NO:2 comprising a substitution, deletion, and/or insertion of one or more amino acids."

However, Hohn *et al.* do not disclose an isolated trichodiene synthase obtained from a *Fusarium venenatum* strain comprising an amino acid sequence which differs by one, two, three, four, or five amino acids from the amino acid sequence of SEQ ID NO:2, as claimed herein.

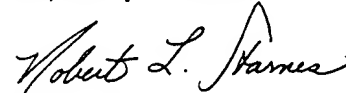
For the foregoing reasons, Applicants submit that the new claims overcome the rejections under 35 U.S.C. § 102. Applicants respectfully request reconsideration and withdrawal of the rejections.

VI. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Date: June 28, 2002

Respectfully submitted,



Robert L. Starnes, Ph.D., Reg. No. 41,324
Novozymes Biotech, Inc.
1445 Drew Avenue
Davis, CA 95616-4880
(530) 757-8100